



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,368	04/20/2006	Frederick R. Kettinger	525.1089-PCT-US	5602
20311 7590 12/20/2007 LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK, NY 10016			EXAMINER VO, TUYEN KIM	
			ART UNIT 2887	PAPER NUMBER
			MAIL DATE 12/20/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/560,368

Applicant(s)

KETTINGER ET AL.

Examiner

Tuyen Kim Vo

Art Unit

2887

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### Acknowledgment

1. This Office Action is responsive to the Amendment filed on 11/05/2007.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 4, 6-8, 11-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus et al. (US 6,543,692 B1, hereinafter "Nellhaus") in view of Verschuur et al. (US 6,168,080 B1, hereinafter "Verschuur").

Re claims 1, 14 and 17, Nellhaus, as shown in figure 10, teaches a solid form drug (72) comprising a core portion (75) having sufficiently low friability to receive a printed or etched marking on a surface thereof; a readable printed or etched marking (data matrix 82) on the surface of the core, the marking providing identification/authentication of the oral dosage form. See column 4, lines 26-50.

However, Nellhaus fails to disclose or suggest the readable printed or etched marking is a covert readable printed or etched marking.

Verschuur teaches a barcode 12 that can be visible or invisible (which serves as covert). See column 4, lines 50-55.

In view of Verschuur's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the readable printed (data matrix 82) of Nellhaus with an invisible barcode (covert readable printed) as taught by Verschuur so that the data cannot be seen or read by a human. Such modification would also provide more security.

Re claim 3, Nellhaus further teaches the printed or etched marking is a barcode (data matrix 82). See column 4, lines 51-54.

Re claim 4, Nellhaus further teaches the barcode is a 2D data matrix barcode. See column 1, lines 13-18.

Re claim 6, Nellhaus further teaches the marking is readable with a barcode scanner (a pen, figure 13). See column 5, line 66 to column 6, line 2.

Re claim 7, Nellhaus further teaches the marking is readable with detection equipment which does not depend upon visible light waves. See column 2, lines 29-35 and column 3, lines 15-19.

Re claims 8 and 20, Nellhaus further teaches a covert marking thereon (hybrid data matrix symbol 90, figure 12). See column 5, lines 49-57.

Re claims 11 and 18, Nellhaus further teaches the surface of the core further comprises a debossed region (icon 75, figure 10, which serves as a debossed region) into which the printed or etched marking is place. See column 4, lines 44-47.

Re claim 12, Nellhaus further teaches the debossed region has a substantially horizontal plane with respect to the center of the core. See figure 10; column 4, line 44-47.

Re claims 13, 15, 16 and 21, Nellhaus further teaches the core has an ink coating applied to a portion thereof to the marking being applied thereto. See column 3, lines 10-22.

4. Claims 2, 5, 19, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Verschuur as applied to claims 1 and 14/20 above, and further in view of Sullivan et al. (US 5,992,742, hereinafter "Sullivan").

Re claims 2 and 19, the teachings of Nellhaus as modified by Verschuur have been discussed above. However, Nellhaus as modified by Verschuuer fails to teach the core is film coated prior to the printed or etches marking being applied thereto.

Sullivan, in the same field of endeavor, teaches a barcode is printed on a label of a pill, which has a code-receiving layer (a core portion) that has a film (a protein based film) coated prior to the printed being applied thereto. See column 11, lines 36-42.

In view of Sullivan's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus as modified by Verschuur to employ the film coated on the core portion as taught by Sullivan so that to easily adhere to the pill which marking can be easily applied thereon. See column 11, lines 36-55 of Sullivan.

Re claim 5, Sullivan further teaches the film coat contains a colorant (the gelatin film has slightly yellow color, see Webster's II, new college dictionary, Houghton Mifflin Company, Boston, New York, Copyright © 1995, page 464). See column 11, lines 36-38.

Re claims 23 and 24, the teachings of Nellhaus as modified by Verschuur have been discussed above. However, Nellhaus as modified by Verschuuer fails to teach the film coating. Nellhaus also teaches the different sizes (concentrating) of the marking such as 4x4, 5x5,...etc..., see column 1, lines 25-62. Therefore, to provide the marking with the range of about 2 to about 5 ppm is obvious from the different sizes of Nellhaus since it is just a variation of sizing.

Sullivan teaches a film (a protein based film such as keratin or gelatin film) coating on the code-receiving layer. See column 11, lines 36-42.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus as modified by Verschuur to employ the film coated on the core portion (code-receiving layer) as taught by Sullivan so that to easily adhere to the pill which marking can be easily applied thereon. See column 11, lines 36-55 of Sullivan.

5. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Verschuur as applied to claims 1/8 above, and further in view of Johnson et al. (US 6,171,618 B1, hereinafter "Johnson").

Re claim 9, the teachings of Nellhaus as modified by Verschuur have been discussed above. However, Nellhaus as modified by Verschuuer fails to teach the covert marking (hybrid data matrix symbol 90, figure 12) is detectable by aroma or taste.

Johnson teaches a taste masking layer can be added to a tablet. See column 12, lines 65-67; column 15, lines 57-61.

In view of Johnson's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus as modified by Verschuur by providing the taste masking layer as taught by Johnson to the cover marking of Nellhau as modified by Verschuur in order to reduce/eliminate the bitter taste of the medicine/pill when the patient places the medicine/pill in his/her mouth. Such modification would further encourage the children/minors of taking the flavored medicine/pill when needed.

Re claim 10, the teachings of Nellhaus as modified by Verschuur have been discussed above. However, Nellhaus as modified by Verschuuer fails to teach the covert marking (hybrid data matrix symbol 90, figure 12) is detectable using HPLC.

Johnson teaches a HPLC system uses to monitor or detect the dosage.

In view of Johnson's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the covert marking of Nellhaus as modified by Verschuur so that it can be detected by HPLC as taught by Johnson since HPLC is used to monitor or detect the chemical using UV detecting and such modification of the covert marking of Nellhaus as modified by Verschuur would not involve any inventive feature.

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Verschuur as applied to claims 14/15 above, and further in view of Krubert (US 4,578,273).

Re claim 22, the teachings of Nellhaus as modified by Verschuur have been discussed above. However, Nellhaus as modified by Verschuur fails to teach the pad printing is applied using an Opacode ink.

Krubert teaches a pad printing is applied using an opacode ink. See column 6, lines 7-13.

In view of Krubert's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus as modified by Verschuur by using the opacode ink as taught by Krubert since Opacode ink is FD&C approved and it may be easily and rapidly printed without runs, smearing or blotting on the product. See column 1, lines 49-58 of Krubert.

### ***Response to Arguments***

7. Applicant's arguments with respect to Nellhaus fails to teach "the marking being a covert marking" in light of claims 1 and 14 have been considered but are moot in view of the new ground(s) of rejection. The limitation has now been treated on the merit as seen above.



***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuyen Kim Vo whose telephone number is 571-270-1657. The examiner can normally be reached on Monday - Friday, 7:30a.m. - 5:00p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Paik can be reached on 571-272-2404. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/560,368  
Art Unit: 2887

Page 9

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*HW.*  
Tuyen Kim Vo  
Patent Examiner  
Art Unit 2887  
December 17, 2007.

*[Signature]*  
STEVEN S. PAIK  
PRIMARY EXAMINER